EXHIBIT E

Ex 5

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	
Plaintiff,	Crim. No.
v.	Violations: Title 21, United States Code Sections 331(a), 331(d), 352(f)(1), and 355(a)
WARNER-LAMBERT COMPANY LLC	
Defendant.	

INFORMATION

THE UNITED STATES ATTORNEY FOR THE DISTRICT OF MASSACHUSETTS CHARGES THAT:

GENERAL ALLEGATIONS

At all times material to this Information, unless otherwise alleged:

BACKGROUND

1. WARNER-LAMBERT COMPANY LLC (hereinafter "WARNER-LAMBERT"), was a corporation operating and existing under the laws of the State of Delaware. Its principal place of business was Morris Plains, New Jersey. WARNER-LAMBERT's Parke-Davis Division was engaged in, among other things, the development, manufacture, promotion, sale, and interstate distribution of prescription drugs intended for human use in the United States. WARNER-LAMBERT's pharmaceutical manufacturing facilities were located in Puerto Rico, from which it shipped products to all fifty states and the District of Columbia.

2. The Federal Food, Drug and Cosmetic Act ("FDCA"), among other things governs the lawful interstate distribution of drugs for human use. As codified at Title 21, United States Code, Sections 331 et seq., and specifically at § 355(b), the FDCA, and its implementing regulations, require that before a new drug may legally be distributed in interstate commerce, a sponsor of a new drug product must submit a New Drug Application ("NDA").

3. The FDCA required, at 21 U.S.C. § 355, that the NDA sponsor submit to the United States Food and Drug Administration ("FDA"), as part of an NDA, proposed labeling for the proposed intended uses for the drug which included, among other things, the conditions for therapeutic use. The NDA must also provide, to the satisfaction of FDA, data generated in

randomized and well-controlled clinical trials that demonstrates that the drug will be safe and effective when used in accordance with the proposed labeling.

4. The FDCA, at 21 U.S.C. § 355, prohibited the introduction into interstate commerce of any new drug, unless an approval of an NDA is effective. Only after the NDA, including the proposed labeling, was reviewed and approved by FDA, was the sponsor permitted by law to promote and market the drug, and only for the medical conditions of use specified in the approved labeling, for which use FDA had found sufficient evidence of safety and effectiveness. Uses unapproved by FDA, not included in the drug's approved labeling, are known as "unapproved uses" or "off-label uses."

5. The FDCA, and the regulations promulgated thereunder, required that in order to label or promote a drug for a use different than the conditions for use specified in the approved labeling, the sponsor had to file a new NDA, or amend the existing NDA, by, among other requirements, submitting the newly proposed indications for use and evidence, in the form of randomized and well-controlled clinical studies, sufficient to demonstrate that the drug would be safe and effective for the newly proposed therapeutic use or uses. Only upon approval of the new NDA could the sponsor promote the drug for the new intended use.

6. The FDCA, at 21 U.S.C. § 352(f)(1), provided that a drug was misbranded if, among other things, the labeling did not contain adequate directions for use. As the phrase is used in the FDCA, adequate directions for use cannot be written for medical indications or uses for which the drug had not been proven to be safe and effective through well-controlled clinical studies because that would be misleading under Section 352(a).

7. The FDCA, 21, U.S.C. §§ 331(a)(d), 333(a), and 355, prohibits the distribution in interstate commerce of an unapproved new drug or of a misbranded drug.

8. In or about 1993, WARNER-LAMBERT submitted an NDA for approval of a drug called Neurontin (also known by the chemical name gabapentin), which was a new drug within the meaning of 21 U.S.C. § 321(p) and 21 C.F.R. § 310.3 (n)(4) and (5). In that application, WARNER-LAMBERT sought to demonstrate the drug's safety and efficacy for, and sought approval for, use only as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy. On or about December 30, 1993, FDA approved Neurontin for that specific use only. This approved use for Neurontin will be referred to throughout this Information as the "Approved Use." Because WARNER-LAMBERT had not sought approval of any other uses nor submitted information in its NDA which demonstrated the safety and efficacy of Neurontin for any such uses, Neurontin was not approved for any use or condition other than the Approved Use. Further, Neurontin was not, pursuant to 21 U.S.C. § 355(i), exempt from the prohibition of introducing into interstate commerce a new drug for medical indications beyond the conditions prescribed, recommended, or suggested in the approved labeling thereof.

9. As described in this Information, from at least June of 1995 through at least August 20, 1996, unapproved uses for Neurontin included post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, bipolar disorder, alcohol withdrawal syndrome, amyotrophic lateral sclerosis (ALS), spinal cord injury, essential tremor, restless leg syndrome, reflex sympathetic dystrophy (RSD); and migraine headaches, among other uses.

These and other unapproved uses for Neurontin will be collectively referred to in this Information as the "Unapproved Uses."

10. WARNER-LAMBERT did not file a new NDA seeking FDA approval for any of these Unapproved Uses during the time period addressed in this Information. Of these Unapproved Uses, only post-herpetic neuralgia has ever received FDA approval, and that approval was applied for and received after the events described in this Information.

WARNER-LAMBERT'S STRATEGY FOR NEURONTIN

11. WARNER-LAMBERT conducted evaluations of the market potential for certain of the Unapproved Uses for Neurontin, including but not limited to: post-herpetic neuralgia, painful diabetic neuralgia, anxiety disorder, social phobias, and bipolar disorder.

12. In or about the fall of 1995, WARNER-LAMBERT's Southeast Customer Business Unit ("SECBU") created a planning document regarding Neurontin, which included a page titled: "SECBU RIGHT ON THE MARK WITH NEURONTIN AND PAIN" over a picture of a target and listed "Neurontin for Pain Strategies" including conference calls on pain and a pain consultant meeting.

13. Certain of WARNER-LAMBERT's annual strategic plans and other marketing planning documents for Neurontin included quarterly and annual goals, objectives, strategies, and tactics for increasing sales of the Unapproved Uses of the drug. The marketing plans budgeted for and funded these tactics.

14. From early 1995, on repeated occasions, WARNER-LAMBERT determined not to seek FDA approval for certain Unapproved Uses.

15. In or about April and May of 1995, WARNER-LAMBERT performed a Marketing Assessment of proposed psychiatric indications for Neurontin. In that Marketing Assessment, WARNER-LAMBERT forecast potential revenue from Neurontin for bipolar and anxiety treatment under two scenarios: with and without FDA approval. WARNER-LAMBERT's Neurontin Development Team and New Product Committee reviewed the potential psychiatric uses and concluded that the company would not seek approval to promote and sell the drug for these Unapproved Uses.

16. In or about July of 1995 WARNER-LAMBERT's assessment of Neurontin's market potential for neuropathic pain was distributed to its Neurontin Development Team and to a WARNER-LAMBERT Vice President for Marketing. That assessment stated that "there is no intention to fully develop the indication at this point." Full development would have required submission of an NDA to FDA for approval.

17. One of the principal factors WARNER-LAMBERT considered in determining whether to seek approval for Neurontin for other uses was the short patent protection available for Neurontin. Another factor was the negative impact such approval might generate on potential sales of another drug that WARNER-LAMBERT had been developing. The company expected this new drug would be approved by FDA not only for epilepsy but also for a variety of uses beyond Neurontin's Approved Use.

18. Once Neurontin's patent expired, other companies could seek approval to distribute generic equivalents of Neurontin. Such approval, however, would be limited to the approved therapeutic use for Neurontin set forth in WARNER-LAMBERT's original NDA approval for Neurontin. If WARNER-LAMBERT sought and obtained approval for any of the

Unapproved Uses, then upon expiration of the patent, generic equivalents of Neurontin could also be sold for those Unapproved Uses. WARNER-LAMBERT was concerned that under those circumstances the generic equivalents would undermine sales of the new drug that was under development.

WARNER-LAMBERT'S PROMOTION OF NEURONTIN FOR UNAPPROVED USES

19. From in or about June of 1995 through in or about August 20, 1996, by certain of the conduct described in greater detail below, WARNER-LAMBERT promoted the sale and use of Neurontin for certain conditions other than the Approved Use in Massachusetts and elsewhere:

OFF-LABEL PROMOTION THROUGH SALES REPRESENTATIVES

20. In October 1995, a member of WARNER-LAMBERT's Epilepsy Disease Team circulated a memorandum to a group including other senior members of WARNER-LAMBERT's Epilepsy Disease Team noting that data purchased from an outside vendor showed that doctors had reported that the main message of certain sales pitches (known as "details"), given by 10 of 50 WARNER-LAMBERT sales representatives for whom data was available in a two month period, was for off-label use of Neurontin. Nine were for pain and one was for reflex sympathetic dystrophy, a painful nerve damage syndrome.

21. On or about July 10, 1996, a WARNER-LAMBERT sales representative met with a doctor in Monroe, Louisiana, and detailed a doctor on Neurontin for the treatment of pain.

22. Also in 1996, a sales representative created a document that stated that sales representatives could ask doctors during a Neurontin detail if they ever used other anti-epileptic drugs for painful neuropathies and could mention that approximately 35% of all Neurontin use is non-seizure. This same document, entitled "Neurontin Can Do/Can't Do," stated that sales

representatives could do lunch programs on Neurontin and pain. The document indicated that it was to be forwarded to the Northcentral Customer Business Unit.

OFF-LABEL PROMOTION THROUGH MEDICAL LIAISONS

23. WARNER-LAMBERT employed "medical liaisons" who were presented to physicians as employees of the company's Medical and Scientific Affairs Department. On the following occasion, a WARNER-LAMBERT medical liaison promoted Neurontin for Unapproved Uses:

(a) In or about June of 1996, a WARNER-LAMBERT sales representative requested that a WARNER-LAMBERT medical liaison make a presentation at Longwood Gardens in Kennett Square, Pennsylvania, to a group of physicians who were members of a local medical society.

(b) The sales representative and the medical liaison selected the topic for the presentation to the local medical society. After deciding in consultation with the sales representative that Neurontin would be the topic of the presentation, the medical liaison prepared the presentation.

(c) Among the topics of the presentation was the use of Neurontin for Unapproved Uses.

(d) During the presentation, in the presence of the sales representative, the medical liaison promoted the use of Neurontin in the treatment of a number of Unapproved Uses.

(e) After the presentation, a WARNER-LAMBERT Medical Director praised the event as "another great example of use of the medical liaisons" and an Area Business Manager called it an "outstanding utilization of . . . one of the medical affairs liaisons."

24. In or about May 1996, a WARNER-LAMBERT Medical Director based in the Northeast CBU sent a voicemail message to the Medical Liaisons in the Northeast CBU in which he stated:

> What we'd like you to do is, any time you're called out just make sure that your main focus out of what you're doing is on Neurontin . . . When we get out there, we want to kick some ass, we want to sell Neurontin on pain. All right? And monotherapy and everything that we can talk about, that's what we want to do.

One or more Medical Liaisons in the Northeast CBU interpreted this statement to mean that he or she should promote Neurontin for Unapproved Uses and thereafter, in or about May and June 1996, promoted Neurontin for neuropathic pain, an unapproved use.

OFF-LABEL PROMOTION THROUGH CONSULTANTS' MEETINGS AND ADVISORY BOARDS

25. WARNER-LAMBERT organized a consultant meeting at the Jupiter Beach Resort in Palm Beach, Florida on April 19-21, 1996. Approximately 42 physicians attended the meeting, including nine physicians who made presentations relating to Unapproved Uses of Neurontin.

26. WARNER-LAMBERT invited certain doctors to this meeting based upon their history of writing a large number of prescriptions for Neurontin or similar drugs. As part of this event, WARNER-LAMBERT paid for accommodations and meals for the invited doctors and

their spouse or guest, and paid an honorarium to each of the doctor attendees. Doctors who acted as faculty were paid between $1,500 and $2,000.

27. Among the presentations made to the physicians in attendance was one relating to Unapproved Uses entitled "Reduction of Pain Symptoms During Treatment with Gabapentin." In the meeting's agenda, this presentation was listed as "Anticonvulsant Advances." During this presentation, Neurontin was promoted for use in the treatment of pain.

28. Another presentation made at the Jupiter Beach conference was entitled "Anticonvulsant Advances: Nonepileptic Uses of Anti Epileptic Drugs." During this presentation, Neurontin was promoted for use in the treatment of essential tremor, episodic dyscontrol, and pain.

29. On or about May 8, 1996, following the Jupiter Beach conference, WARNER-LAMBERT circulated to employees in the Northeast region the agenda to the meeting, specifying the off-label topics, the faculty list, the attendee list and presentation abstracts discussing the off-label content of the presentations. WARNER-LAMBERT told its employees that: "[t]he meeting was a great success and the participants were delivered a hard-hitting message about Neurontin." WARNER-LAMBERT distributed to these employees a form entitled "Jupiter Beach Trending Worksheet" which was intended to be used to gauge the effect of the meeting on the prescribing by doctors who attended the Jupiter Beach meeting.

30. From August 1-5, 1996, WARNER-LAMBERT organized an "advisory board meeting," in Atlanta, Georgia in conjunction with the 1996 Summer Olympics. WARNER-LAMBERT expressly instructed several of the physician speakers to address some of the Unapproved Uses.

31. During that meeting, WARNER-LAMBERT hosted doctors at the Chateau Elan Winery and Resort, in Atlanta, Georgia, and paid all the expenses for eighteen "consultants" and their spouses to attend the Olympics, including tickets to the closing ceremonies. The company had already had numerous opportunities to consult with the doctors and, in fact, many of them had spoken on WARNER-LAMBERT's behalf at prior meetings.

32. Certain of the physician speakers promoted Neurontin for unapproved uses in their presentations.

OFF-LABEL PROMOTION THROUGH TELECONFERENCES

33. In or about January, 1996, a WARNER-LAMBERT Vice President of the Southeast Customer Business Unit sent a memorandum to WARNER-LAMBERT sales representatives listing certain goals, including: "Utilize the Medical Liaison Group to target the Neurontin, Pain & Psychiatric market. Objective to conduct twice weekly Pain Teleconferences moderated by key Neuro Consultants. Goals 250 Physicians Participants quarterly."

34. On or about March 1, 1996, WARNER-LAMBERT sponsored such a teleconference moderated by a WARNER-LAMBERT employee with a pain specialist as a speaker on Neurontin. The speaker promoted Neurontin for the treatment of pain to doctors participating in the teleconference.

35. On or about March 28, 1996, a WARNER-LAMBERT Medical Director in the Northcentral Customer Business Unit sent a memorandum to WARNER-LAMBERT Medical Liaisons in that unit instructing them to hold a series of teleconferences with doctors to provide clinical updates on Neurontin, including monotherapy epilepsy data and non-epilepsy use data entitled "Neurontin, A Clinical Update."

36. In or about May, 1996, a WARNER-LAMBERT Medical Director held such a teleconference entitled "Neurontin, A Clinical Update" in which the Medical Director promoted off-label uses of Neurontin to the doctors participating in the teleconference.

COUNT ONE: 21 U.S.C. §§ 331(d), 333(a)(2) & 355(a)

(Distribution of an Unapproved New Drug)

37. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

38. Beginning as early as in or about April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts, and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses. No approval, pursuant to 21 U.S.C. § 355, was in effect with respect to Neurontin for use in these conditions.

All in violation of 21 U.S.C. §§ 331(d), 333(a)(2), and 355(a).

COUNT TWO: 21 U.S.C. §§ 331(a), 333(a)(2) & 352(f)(1)

(Distribution of a Misbranded Drug: Inadequate Directions for Use)

39. The allegations contained in paragraphs 1 through 36 are realleged and incorporated herein as if set forth in full.

40. Beginning as early as April 1995, and continuing thereafter until at least in or about August 20, 1996, in the District of Massachusetts and elsewhere,

WARNER-LAMBERT,

after previously having been convicted of violating the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 333, did introduce and cause the introduction into interstate commerce from Puerto Rico and elsewhere, directly and indirectly, into Massachusetts and elsewhere, quantities of Neurontin, a drug within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(p), which drug was intended for use for the treatment of neuropathic pain, bipolar disorder, as monotherapy for epilepsy, and other Unapproved Uses, and which was misbranded within the meaning of 21 U.S.C. § 352(a), in that Neurontin's labeling lacked adequate directions for such uses.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f)(1).

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DISTRICT OF MASSACHUSETTS

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May 13, 2004